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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/809,638 | 03/24/2004 | Jun Feng | DPP-IV-5004-C3 | 8935 |
| 32793 | 7590 | 08/04/2006 | EXAMINER | |
| TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121 | | | HABTE, KAHSAY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |
| DATE MAILED: 08/04/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/809,638

Applicant(s)

FENG ET AL.

Examiner

Kahsay Habte

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-46 are pending in this application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-46 (in part), drawn to [1,2,4]thiadiazine compounds of the formulae XXXVII, XXXVIII and XXXIX with $Q = SO$ or SO_2 and $J = M = K = L = N$, classified in class 544, subclass 12.
 - II. Claims 1-46 (in part), drawn to [1,2,4]thiadiazine compounds of the formulae XXXVII, XXXVIII and XXXIX with $Q = SO$ or SO_2 and at least three of $J = M = K = L = N$, classified in class 544, subclass 12.
 - III. Claims 1-46 (in part), drawn to [1,2,4]thiadiazine compounds of the formulae XXXVII, XXXVIII and XXXIX with $Q = SO$ or SO_2 and at least two of $J = M = K = L = N$, classified in class 544, subclass 12.
 - IV. Claims 1-46 (in part), drawn to pyrimido[5,4-d]pyrimidin-4(3H)-one compounds with $Q = C=O$, CS , or $C=NR_9$, and $J = L = N$, and $K = M = CR_{12}$, classified in class 544, subclass 256, among others.
 - V. Claims 1-46 (in part), drawn to pyrimido[5,4-c]pyridazin-8(7H)-one compounds with $Q = C=O$, CS , or $C=NR_9$, and $J = K = N$, and $L = M = CR_{12}$, classified in class 544, subclass 235.

- VI. Claims 1-46 (in part), drawn to pyrimido[4,5-d]pyrimidin-4(3H)-one compounds with $Q = C=O$, CS, or $C=NR_9$, and $K = M = N$, and $J = L = CR_{12}$, classified in class 544, subclass 256.
- VII. Claims 1-46 (in part), drawn to pyrimido[4,5-c]pyridazin-5(6H)-one compounds with $Q = C=O$, CS, or $C=NR_9$, and $L = M = N$, and $J = K = CR_{12}$, classified in class 544, subclass 236.
- VIII. Claims 1-46 (in part), drawn to pyrimido[5,4-d][1,2,3]triazin-8(7H)-one compounds with $Q = C=O$, CS, or $C=NR_9$, and $J = K = L = N$, and $M = CR_{12}$, classified in class 544, subclass 184, among others.
- IX. Claims 1-46 (in part), drawn to pyrimido[4,5-e][1,2,4]triazin-8(7H)-one compounds with $Q = C=O$, CS, or $C=NR_9$, and $J = K = M = N$, and $L = CR_{12}$, classified in class 544, subclass 184.
- X. Claims 1-46 (in part), drawn to pyrimido[5,4-e][1,2,4]triazin-5(6H)-one compounds with $Q = C=O$, CS, or $C=NR_9$, and $J = L = M = N$, and $K = CR_{12}$, classified in class 544, subclass 184.
- XI. Claims 1-46 (in part), drawn to pyrimido[4,5-d][1,2,3]triazin-5(6H)-one compounds with $Q = C=O$, CS, or $C=NR_9$, and $K = L = M = N$, and $J = CR_{12}$, classified in class 544, subclass 184.
- XII. Claims 1-46 (in part), drawn to pyrimido[5,4-e][1,2,3,4]tetrazin-8(7H)-one compounds with $Q = C=O$, CS, or $C=NR_9$, and $J = K = L = M = N$, classified in class 544, subclass 179, among others.

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XIII. Claims 1-46 (in part), drawn to others (e.g. $L = N$ and $J = K = M = CR_{12}$ and $Q = SO$; $K = N$, $J = L = M = CR_{12}$ and $Q = SO$, etc.) classified in class 544, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Groups I-XIII are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of Q, J, K, L, M in formula XXXVII, XXXVIII and XXXIX do not belong to the same recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others. Each groups comprises a different heterocyclic core system. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structure equivalents of each other.

The inventions are distinct, each from the other because of the following reasons:

inventions I-XIII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the heterocyclic core of the structure given in claim 1 is the ring including radicals J, K, L

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and M. This bicyclic rings are chemically non-equivalent and are not art-recognized as sharing the same biological properties. Inventions I-XIII have acquired a separate status in the art as shown by their different classification. The basic names of these heterocyclic compounds differ, thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Although some groups are classified together these are patentably distinct ring systems, *i.e.* a reference against one ring would not be a reference against another. These will also raise separate issues of enablement for making and enablement for using. The basic names of these heterocyclic compounds differ, thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

In addition, applicants are required to elect a single disclosed species. Note that further restriction may be required.

A telephone call was not made to applicants because the restriction requirement is not simple to address over the phone.

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Káhsay Habte', is positioned above the printed name.

Káhsay Habte
Primary Examiner
Art Unit 1624

August 2, 2006